IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Thomas RICHARDSON et al.

Serial No.: 10/058,835 Group Art Unit: 1635

Filed: January 30, 2002 Examiner: Tracy A. Vivlemore

For: METHODS FOR SUSTAINED RELEASE LOCAL DELIVERY OF DRUGS FOR ABLATION OF UNWANTED TISSUE

PETITION TO DIRECTOR UNDER 37 C.F.R. §1.181 TO WITHDRAW RESTRICTION REQUIREMENT

MAIL STOP AMENDMENT
Commissioner for Patents
Box 1450
Alexandria, Virginia 22313-1450

Applicants hereby petition to the Director under 37 C.F.R. §1.181 from the final restriction requirement of the Examiner set forth in the Office Action mailed August 12, 2004, from which reconsideration was requested in the Reply filed February 10, 2005, from which the requirement was repeated in the Office Action of May 17, 2005.

Statement of Facts

1. Claim 1 recites a method and all other pending claims, i.e., claims 2-17 and 24-27 are ultimately dependent upon claim 1 and are directed to subject matter within the scope of the claim 1 genus.

2. Within the genus of claim 1, encompassing all the subject matter of all the pending claims, the Examiner has made a restriction requirement between every specific agent which is a "substance which eliminates or prevents formation of the cells of the undesired tissue" and its resulting effect. Thus, each method of the invention using every different substance having such property is restricted from each other method of the invention

using every other substance which exhibits such property. The number of groups into which the invention is restricted is undeterminable but would be a very large number of groups.

3. Pursuant to the Restriction Requirement, applicants elected with traverse the group wherein the "substance which eliminates or prevents formation of the cells of the undesired tissue" is TNF-alpha which is effective to remove undesired fat tissue. See the Response to Requirement for Restriction, filed June 21, 2004.

4. Applicants substantively traversed the Restriction Requirement in the above-cited Response and in the Reply filed February 10, 2005. The requirement, however, was maintained.

5. Claim 32, proposed to be added by the Reply After Final Rejection filed September 19, 2005, is also within the scope of genus claim 1 and would encompass the elected invention.

Point to be Reviewed

Applicants request that the propriety of the Restriction Requirement currently maintained by the Examiner be reviewed.

Action Requested

Applicants request that the Restriction Requirement be withdrawn, in full.

Discussion

Applicants disagree with the allegations in the Office Actions that the subject matter within the same generic claim 1 covers a number of unrelated inventions. The alleged basis for the restriction was that a method according to the claimed invention using one type of a "substance which eliminates or prevents formation of the cells of the undesired tissue" is

"unrelated" to the same method according to the invention with a different type of such substance. It was alleged that inventions are "unrelated" if they have different functions, different effects or different modes of operation. And it was alleged that, apparently, any difference in the type of "substance which eliminates or prevents formation of the cells of the undesired tissue" results in a different mode of operation.

Applicants urge that the wrong PTO practice regarding "unrelated inventions" was applied and further that it was not applied in a reasonable manner.

The "unrelated" standard applied to support the restriction appears in MPEP §806.04. However, this section does not relate to the instant fact situation. The part of MPEP §806.04 states:

> (A) Two different combinations, not disclosed as capable of use together, having different modes of operation, different functions or different effects are independent. An article of apparel such as a shoe, and a locomotive bearing would be an example. A process of painting a house and a process of boring a well would be a second example.

This is clearly not the applicable section for the instant claims. There are not "two different combinations" involved here and the instant facts are nowhere near the type of situation given in the examples. The Examiner never identified what are the "two different combinations" which give rise to the restriction. Instead, the instant facts clearly relate to a genus-species situation, i.e., all the "substances" which are being restricted from one another are within the genus of a "substance which eliminates or prevents formation of the cells of the undesired tissue." Because there are not two different combinations, the fact situation is governed by the genus-species practice, as follows:

> Where inventions as disclosed and claimed are both (A) species under a claimed genus and (B) related, then the question of restriction must be determined by both the practice applicable to election of species and the practice applicable to other types of restrictions such as those covered in MPEP § 806.05 -§ 806.05(i). If restriction is improper under either practice, it should not be required.

None of the situations under MPEP §806.05 - §806.05(i) apply here; nor has there been any allegation by the Examiner that any of these apply. Thus, only election of species practice would be proper.

Further, it is urged that, in any event, the standard is being unreasonably applied. Under the theory of the currently alleged restriction, every species of every genus would always be restricted from each other. Every compound works somewhat differently from even closely related compounds. But this is not the basis for stating that they show a different mode of operation. Instant claim 1 sets forth the function that shows the substances all have the same general mode of operation, i.e., they eliminate or prevent formation of the cells of the undesired tissue.

It is not improper to define the substance according to its function. This is especially the case here, since the novelty of the invention does not lie in the particular substance used but in the manner of its local administration and local effect. The claims are not merely to any method of "eliminating or reducing normal but undesired tissue in a patient" but only those methods which comprise the clearly defined and distinct steps of claim 1, i.e.:

> "administering a controlled release formulation to the patient by injection at a local area containing the undesired tissue such that the undesired tissue in the local area is eliminated or reduced, said formulation comprising a substance which eliminates or prevents formation of the cells of the undesired tissue, said substance being provided in a controlled release carrier."

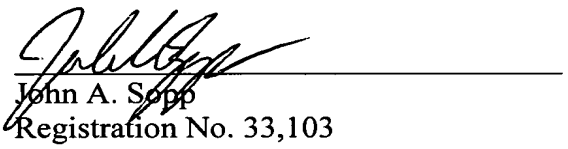
That the restriction requirement made here is unreasonable is further evidenced by the fact that, if upheld, the requirement would force the applicants to file a huge number of different applications to obtain patent coverage of single inventive concept, i.e., applicants would have to file a separate application for the method using each specific species of substance which eliminates or prevents formation of the cells of the undesired tissue. Thus,

in addition to the absence of a basis for the restriction in the law or in the PTO's own practice rules or procedures, it is urged that the restriction also would be inequitable to the applicants.

For all of the above reasons, withdrawal of the restriction requirement is earnestly petitioned.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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